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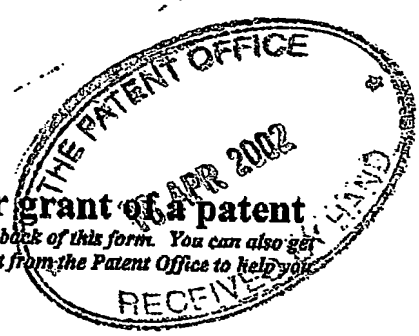

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference P104001GB/ISH/EC/47771

2. Patent application number *(The Patent Office will fill in this part)* 0208704.7

16 APR 2002

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Futura Medical Developments Limited
Surrey Technology Centre
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United Kingdom

Patents ADP number *(if you know it)* 8364523001

If the applicant is a corporate body, give the country/state of its incorporation: United Kingdom

4. Title of the invention: Condom

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

WITHERS & ROGERS
Goldings House
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SE1 2HW

Patents ADP number *(if you know it)* 1776001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(answer 'Yes' if:*
a) any applicant named in part 3 is not an inventor, or
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Continuation sheets of this form	
Description	5
Claim(s)	1
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Request for preliminary examination and search *(Patents Form 9/77)*	
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11. I/We request the grant of a patent on the basis of this application.

Signature Withers & Rogers Date 16 April 2002

12. Name and daytime telephone number of person to contact in the United Kingdom — I S Harrison — 0117 925 3030

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P104001GB

Condom

This invention relates to condoms and is particularly intended to provide a condom for provision of sexual stimulation to the female partner of the user, in order to alleviate female sexual dysfunction or to enhance sexual pleasure.

It is recognised that female sexual dysfunction is a complex condition which, due to its various causes, cannot readily be treated by use of a particular drug or device. Nevertheless, an increase in vaginal blood flow and clitoral engorgement is known to be associated with increased vaginal secretions, a decrease in dyspareunia and increases in clitoral sensation, orgasmic response and sexual desire. It is an object of the present invention, therefore, to provide a means of stimulating the female genitalia during intercourse to increase vaginal blood flow.

In one aspect, the invention provides a male condom which includes a textured region to its external surface, the textured region comprising a vasodilator active compound.

The textured region is preferably disposed towards the open end of the condom whereby, in use during intercourse, the textured region makes contact with the proximal region of the vagina, such that the vasodilator is absorbed through the lining of the vagina to stimulate and increase the flow of blood in this region and through the clitoris to promote engorgement thereof which, itself, will lead to further stimulation and result in increased vaginal secretions. Symptoms associated with female inorgasmia will thus be alleviated.

The textured region of condoms according to the invention will not only act to release the vasodilator but will also provide mechanical stimulation of the proximal region of the vagina during intercourse, thus additionally creating enhanced levels of stimulation.

By use of the invention, a further advantage is that increased vaginal secretions result in increased lubrication between the wall of the vagina and the condom resulting in a lower rate of condom failure due to rupture.

In condoms according to the present invention, the active compound may be contained or impregnated in or coated on the textured region of the condom. The textured region may be formed integrally with the condom itself or separately applied thereto after the condom itself is manufactured. The vasodilator preferably includes a carrier material with which the vasodilator compound is miscible but which will release the vasodilator active compound when in contact with body tissue. The vasodilator is thereby localised to a

particular region, preferably towards the open end of the condom and on the external surface thereof, so that during intercourse the active compound is brought in contact with the proximal region of the vagina so as to stimulate and increase the blood flow in the labia and through the clitoris. The texturing as applied to the condom may comprise ribs or an array of individual protrusions or may comprise merely a roughened surface region, formed either by imparting a pattern to the surface of the condom or by application to the surface thereof of a particulate material or a material having a high coefficient of surface friction, such as a highly plasticised elastomer. The textured surface may be formed by manufacturing the condom on a mandrel or mould having an appropriate pattern of ribs, dots or other texturing etched into or embossed on its surface or by applying to the condom a material which results in a textured surface, for example by extruding a thin stream of the material from a nozzle so as to form a series of rings around the condom or by spraying the material in such a way that the surface becomes textured. A suitably textured extruded section can be applied direct to the condom at the time of its manufacture or subsequently, either by direct bonding or by the use of a pressure-sensitive, hot-melt or other suitable type of adhesive. Alternatively, a coating of a material can be applied for example by spraying, the coating then having a texturing applied to it by contact with a suitably patterned die so as to mould the surface in the desired textured shape.

The textured surface may be formed from one or more layers of material including the material in which the condom itself is formed. The material of at least one such layer should be miscible with the vasodilator and should allow the vasodilator to be absorbed by skin or tissue when brought in contact with the condom. Preferably, the material from which the condom is formed, either natural rubber latex or a synthetic rubber-like material, and any lubricant used therein, is immiscible with the vasodilator or the vasodilator-containing composition, whereby the vasodilator is restrained from migrating to other parts of the condom other than the zone of application. The material from which the vasodilator-containing layer is formed will depend on the nature of the vasodilator active compound but, for active compounds such as organic nitrates, for example glyceryl trinitrate, suitable materials would include polar elastomers applied to the condom from solution, in the form of an aqueous dispersion of latex or by a hot melt or reactive process. Alternatively, the vasodilator-containing layer can be pre-formed and bonded subsequently to the condom using a suitable adhesive system as necessary.

The vasodilator active compound may comprise any known erectogenic compound which, on absorption through the skin or mucosa, locally enhances blood flow. Such compounds may include nitrates, long and short acting alpha-adrenoceptor blockers, ergot alkaloids, anti-hypertensives and the prostaglandins. Phosphodiesterase inhibitors, particularly type

III and IV and most particularly type V can also be used, either alone or in combination with other vasodilators. Such compounds can be used alone or in combination and, optionally, together with skin penetration enhancers such as azone, dimethylsulfoxide, dimethyl formamide, N,N-dimethylacetamide, declymethylsulfoxide, polyethylene glycol monolaurate, glycerol monolaurate, lecithin and 1-substituted azacyclopheptan-2-one.

Erectogenic compounds that can be incorporated into the condom include vasodilators or related compounds, including the nitrates, long and short acting alpha-adrenoceptor blockers, ergot alkaloids, anti-hypertenives and the prostaglandins. Phosphodiesterase inhibitors, particularly type III and IV and most particularly type V can also be used, either alone or in combination with vasodilators and related compounds.

Useful nitrates and similarly acting compounds include nitro-glycerine, isosorbide dinitrate, erythrityl tetranitrate, amyl nitrate, sodium nitroprusside, molsidomine, linsidomine chlorydrate ("SIN-1"), S-nitroso-N-acetyl-d,1-penicillamine ("SNAP"), S-nitroso-N-cysteine, S-nitroso-N-glutathione ("SNO-GLU") and diazenium diolates ("NONOates"). A particularly useful nitrate is nitro-glycerine.

Natural prostaglandins that can be used include PGE_0, PGE_1, PGA_1, PGB_1, PGF_1alpha, 19-hydroxy-PGA_1, 19-hydroxy-PGB_1, PGE2, PGA_2, PGB_2, 19-hydroxy-PGA_2, 19-hydroxy-PGB_2, PGE_3, PGF_3alpha. Semi synthetic and synthetic prostaglandins such as carboprost tromethamine, dinoprost tromethamine, dinoprostone, lipoprost, gemeprost, metenoprost, sulprostone and tiaprost can also be used. A particularly useful prostaglandin is prostaglandin E_1 (PGE_1) or its synthetic version, alprostadil. Esters of the prostaglandins, such as the methyl and ethyl esters, can also be used.

Suitable alpha-adrenoceptor blockers include phenoxybenzamine, dibenamine, doxazosin, terazosin, phentolamine, tolazoline, prazosin, trimazosin, alfuzosin, tamsulosin and indoramin.

Ergot alkaloids include ergotamine and ergotamine analogs, e.g., acetergamine, brazergoline, bromerguride, cianergoline, delorgotrile, disulergine, ergonovine maleate, ergotamine tartrate, etisulergine, lergotrile, lysergide, mesulergine, metergoline, metergotamine, nicergoline, pergolide, propisergide, proterguride and terguride. A particularly effective alkaloid is yohimbine hydrochloride.

Non-specific phosphodiesterase inhibitors that can be incorporated into the condom include theophylline, IBMX, pentoxifylline and papaverine, and direct vasodilators such as hydralazine. Papaverine is particularly useful either alone or in combination with phentolamine.

Examples of type III phosphodiesterase inhibitors that may be used include bipyridines such as milrinone and amirinone, imidazolones such as piroximone and enoximone, dihydropyridazinones such as imazodan, 5-methyl-imazodan, indolidan and ICI1118233, quinolinone compounds such as cilostamide, cilostazol and vesnarinone, and other molecules such as bemoradan, anergrelide, siguazodan, trequinsin, pimobendan, SKF-94120, SKF-95654, lixazinone and isomazole.

Examples of suitable type IV phosphodiesterase inhibitors include rolipram and rolipram derivatives such as RO20-1724, nitraquazone and nitraquazone derivatives such as CP-77059 and RS-25344-00, xanthine derivatives such as denbufylline and ICI63197, and other compounds such as EMD54622, LAS-31025 and etazolate.

Examples of type V phospodiesterase inhibitors include zaprinast, MY5445, dipyridamole, vardenafil, and sildenafil. Other suitable type V phosphodiesterase inhibitors are disclosed in PCT Publication Nos. WO 94/28902 and WO 96/16644. A particularly useful type V phosphodiesterase inhibitor is sildenafil. Still other type V phosphodiesterase inhibitors useful in conjunction with the present invention include: IC-351 (ICOS); 4-bromo-5-(pyridylmethylamino)-6-[3-(4-chlorophenyl)propoxy]-3(2H)pyridazinone; 1-[4-[(1,3-benzodioxol-5-ylmethyl)amiono]-6-chloro-2-quinazolinyl]-4-piperidine-carboxylic acid, monosodium salt; (+)-cis-5,6a,7,9,9a-hexahydro-2-[4-(trifluoromethyl) -phenylmethyl-5-methyl-cyclopent-4,5]imidazo(2,1-b]purin-4(3H)one, furazlocillin; cis-2-hexyl-5-methyl-3,4,5,6a,7,8,9,9a-octahydrocyclopent[4,5]imidazo[2,1-b]purin-4-one; 3-acetyl-1-(2-chlorobenzyl)-2-propylindole-6-carboxylate; 4-bromo-5-(3-pyridylmethylamino)-6-(3-(4-chlorophenyl) propoxy)-3-(2H)pyridazinone;

1-methyl-5-(5-morpholinoacetyl-2-n-propoxyphenyl)-3-n-propyl-1,6,-dihydro-7H-pyrazolo (4,3-d)pyrimidin-7-one; 1-[4-[1,3-benzodioxol-5-ylmethyl)amino]-6-chloro-2-

quinazolinyl]-4-piperidinecarboxylic acid, monosodium salt; Pharmaprojects No. 4516 (Glaxo Wellcome); Pharmaprojects No. 5051 (Bayer); Pharmaprojects No. 5064 (Kyowa Hakko; see WO 96/26940); Pharmaprojects No. 5069 (Scherin Plough); GF-196960 (Glaxo Wellcome); and Sch-51866.

Other compounds that can be used include nimodipine, pinacidil, cyclandelate, isoxsuprine, chloromazine, haloperidol, Rec15/2739 and trazodone, as well as anti-hyertensive agents including diazoxide, hydralazine and minoxidil.

The activity compound or compounds optionally together with skin penetration enhancers may be applied direct to the appropriate region of the condom or as a composition dispersed or dissolved in a suitable carrier media, for example a gel carrier comprising a liquid medium and a thickening agent.

Embodiments of the invention will now be described by way of example only.

Example 1

A condom having a textured portion towards the open end was made by dipping a former into compounded natural rubber latex, the former having a series of groves etched into its surface so as to form a series of ribs near the open end of the condom. After the condom was removed from the former it was mounted on a mandrel and a thin coating of a plasticised thermoplastic elastomer (a tri-block copolymer of styrene and butadiene) dissolved in a suitable solvent containing glycerol trinitrate absorbed onto lactose was applied by roller to the ribbed portion of the condom. The solvent was evaporated to leave the coating on the textured portion. The condoms were then rolled off the mandrel and lubricated and packed as normal. A water-based lubricant, which is immiscible with glycerol trinitrate, was selected. The presence of the lactose enhanced the texture of the ribs and acted as a source of glycerol trinitrate.

Example 2

A 10 mm wide strip of a plasticised thermoplastic elastomer containing glycerol trinitrate dissolved in monopropylene glycol was extruded onto release paper using a die to form a profile having a number of raised ribs. The extruded strip, still on the release paper, was cut into a number of strips, the length of each strip being the circumference of the condom. Standard, parallel sided, non-ribbed condoms were mounted onto suitable mandrels and the strips were wrapped around the condoms near to the open end. The strips were then made to adhere to the condom by applying a heated roller and the release paper was removed. The condoms were then rolled, lubricated and packed as normal.

Example 3

A standard, un-ribbed condom was mounted on a mandrel and a thin film of a plasticised thermoplastic elastomer dissolved in a suitable solvent was sprayed onto the condom in a narrow band close to its open end. The elastomer contained glycerol trinitrate dissolved in monopropylene glycol. The solvent was removed by evaporation and the mandrel was brought into contact with a hot embossed roller so that the roller pressed onto the band. The mandrel was rotated so as to leave an embossed pattern in the band. The condom was removed from the mandrel and then lubricated and packed.